Washington State Department of Health

ELABORATIONS

News and Issues for Washington's Clinical Laboratories

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Laboratory Conference Highlights: HIPAA

by Leonard Kargacin

Health Insurance Portability and Accountability Act of 1996 (HIPAA). Marguerite Busch, Compliance Officer at Pathology Associates Medical Laboratories in Spokane, presented a session entitled "HIPAA Compliance in the Real World". The following is a synopsis of her presentation.

There are three broad aspects covered by HIPAA

- **Insurance portability:** Guarantees portability of health insurance (removes the "existing condition" clause in health insurance policies)
- **Fraud and abuse:** Reduces occurrence of fraud and abuse
- **Administration simplification:** Mandates regulations to govern privacy, security, and electronic transaction standards. The three key areas under administrative simplification include:
  - **Electronic Data Interchange (EDI**): The computer information services division of your facility will probably deal with this portion. EDI deals with the coding that you use to submit your claims (transaction sets, code sets, and identifiers). **October 16, 2002 implementation date.** ***UPDATE SINCE THE CONFERENCE:*** *The deadline for these standards has recently been extended until October 16, 2003. However, to qualify for this extension, a comprehensive plan detailing the budget, schedule, work plan, implementation strategy and other information must be presented to HHS by October 16, 2002.*
  - **Privacy:** Healthcare providers must not wrongfully disclose individually identifiable health information. There are potential amendments to the Privacy Standards that should be available early in 2002. **APRIL 14, 2003 implementation date**.
  - **Security:** Healthcare providers must protect the healthcare information they maintain or transmit electronically from improper access, alteration, or loss. The security implementation date has not yet been finalized (compliance will be required 2 years after the effective date of the regulation once published). It is anticipated that there will not be a lot of changes from the proposed rules. The security aspects include physical safeguards (who can access information), technical security systems and mechanisms, and administrative procedures.

General information

- The enforcement of HIPAA will be the responsibility of the HHS Office of Civil Rights.
- There are criminal and civil sanctions for HIPAA non-compliance.
- HIPAA supersedes contrary provisions of state law

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Practice Guidelines

The following practice guidelines have been developed by the Clinical Laboratory Advisory Council. They can be accessed at the following website:
www.doh.wa.gov/hsqa/fsl/LQA_Home.htm

Anemia	Point-of-Care Testing
ANA	PSA
Bleeding Disorders	Renal Disease
Chlamydia	STD
Diabetes	Thyroid
Hepatitis	Tuberculosis
HIV	Urinalysis
Lipid Screening	Wellness

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unless state law is more stringent than the federal regulations.

For HIPAA compliance, facilities should have:
- Written standards, policies, and procedures.
- Designated privacy officer/committee.
- Education: Staff at all levels that are affected must be educated on privacy issues.
- Communication: There must be a way for employees to come forward and report problems, violations, etc.
- Auditing and monitoring: Procedures must be audited periodically to make sure they are still working.
- Enforcement/Discipline: If there are violations, are there disciplinary processes in place and are they carried out?
- Corrective action: Change what is not working and make it work better.

Definition of key terms:

Who is covered by HIPAA? Covered entities include:
- All health plans
- All healthcare clearinghouses
- Healthcare providers who transmit health information electronically

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Website addresses:
DOH home page: http://www.doh.wa.gov
LQA home page:
http://www.doh.wa.gov/hsqa/fsl/LQA_Home.htm

Who is not covered by HIPAA?
- Insurance programs other than health insurance (life, property, casualty, disability)
- Worker's compensation programs

What is covered by HIPAA?
- Protected Health Information (PHI): All records and other patient individually identifiable health information (IIHI) held or disclosed by a covered entity in any form, whether communicated electronically, on paper, or orally

  IIHI: health information from an individual including demographic information which could potentially be used to identify an individual. There are 18 items that are considered to be IIHI, including name, address, zip code, names of relatives, name of employer, date of birth, fax number, e-mail address, account number, health plan beneficiary number, medical record number, etc.

Patient rights: Patients must-
- Be educated on privacy protections.
- Have access to their medical records. (They can see, get copies, request amendments, and get a history of non-routine disclosures.)
- Consent before information is released.
- Have recourse if privacy protections are violated.

Treatment, Payment, Operations information can be shared fairly freely similar to what we do now.
- Treatment - provision, coordination, or management of healthcare and related services including consultations and referrals.
- Payment – activities to obtain reimbursement for the provision of healthcare.
- Operations – activities related to QA/QI, outcomes evaluation, competency reviews, medical reviews, legal services, auditing functions, business planning and development, etc.

Use/Disclosure of protected health information (PHI)
- Use – internal sharing, utilization, examination or analysis of PHI.
- Disclosure – external release, transfer, provision of access to, or divulging information to an outside entity.

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Consent vs. Authorization

- Consent – allows the use and disclosure of PHI only for treatment, payment, and other healthcare operations. This form is a one-time general permission form signed by the patient that must be kept on file for 6 years.
- Authorization – allows use and disclosure of PHI for other purposes such as research. The authorization is specific to the purpose and the parties involved. There is a time frame (expiration date) associated with an authorization. Information that can be released without an authorization to outside may be permitted for the following reasons: required by law; related to abuse, neglect, or domestic violence; or needed for public health activities.

The Indirect Treatment Relationship is expected to exempt laboratories from having to obtain a consent form from patients. An indirect treatment relationship is defined as follows:

- The provider delivers care to the individual based on the orders of another healthcare provider; AND
- The provider typically provides services, products, or results directly to another provider who provides the services to the patient.

Laboratories are considered to be in an indirect treatment relationship with the patient. Therefore, it appears that laboratories would **not** need to get signed patient consent forms for laboratory testing. Laboratories can presume that this is the case unless HHS says something differently.

How to get started on the road to implementation and compliance

- Determine HIPAA responsibility and authority.
- Provide training for employees.
- Conduct readiness assessment:
  - Inventory existing policies and procedures.
  - Inventory equipment and software with PHI.
  - Who currently has access to what information; do they need access to all information?
  - Who has physical access to PCs/terminals, fax machines, copiers?
  - Do you send PHI outside of your office laboratory? To whom, in what format, by what means?
  - How do you discard/dispose of patient information? Shred? Recycle? Regular trash?
  - Do you contract with/use these types of services?
    - Legal counsel?
    - Auditors?
    - Vendors who service instruments?
    - Janitoral services?
    - Recycling services?
    - Billing/coding service?
    - Computer interfaces from/to other providers?
- Prepare a list of gaps between current status and HIPAA requirements.
- Prioritize gaps according to the following criteria:
  - Most serious deviations from the rules.
  - Most easily changed/corrected.
  - Most resources needed to comply.
- Formulate timeline and preliminary budget considerations.
- Make recommendations to “decision-making” group.
- Develop an implementation plan.
- Determine responsible departments/individuals to facilitate changes.
- Standardize processes and policies wherever possible by creating templates.
- Establish a realistic time frame.

The HIPAA information discussed above can be scaled to apply to each type and size of organization. Smaller facilities still have to implement the HIPAA regulations. Implementation will be simpler to institute in a smaller office, but the regulations must be implemented. Even if everything is done manually (no computers), the privacy concerns still have to be reviewed and modified as necessary.

HIPAA Resource Websites

www.hhs./gov/ocr/hipaa
www.healthprivacy.org
www.hipaadvisory.com
www.aspe.hhs.gov/admnsimp/index.htm
www.wshima.org
www.healthinfoprogram.com

Laboratory Conference Highlights - Laboratory Reporting of Notifiable Conditions: Electronic Reporting and the Implications of HIPAA

by Leonard Kargacin

Greg Smith, Development Director of the Washington State Department of Health (DOH) Electronic Disease Surveillance System, presented a portion of the session on HIPAA Compliance. His portion dealt with HIPAA in relation to electronic data transfer.

The Washington State Department of Health (DOH) collects information via the notifiable conditions reporting process to assure that patients are receiving the appropriate course of care and to intervene to prevent other people from becoming ill. This active intervention provides prophylactic treatment to people who may have been exposed to something to prevent them from becoming sick. The information helps DOH to evaluate how well and how effectively the resources we have for prevention and education are used.

A variety of entities report notifiable conditions including laboratories, health care providers, health care facilities, veterinarians, and the general public. The authority for notifiable conditions surveillance can be found under WAC 246-101 – Notifiable Conditions and WAC 246-102 – Cancer Surveillance. The specific information contained in these WACs can be found at the following website: www/dpj/wa/gpv/os/policy/246-101.htm.

The DOH is working on a project that will allow laboratories in Washington to report notifiable conditions to the DOH and local health departments electronically. The HIPAA requirements for electronic data interchange have been incorporated into the system.

How does the notifiable condition reporting system work with HIPAA? One of the principle requirements of HIPAA is patient control of disclosure of health related data with limited exceptions (as required by law, and for the purposes of public health). WAC 246-101 requires the notification of these incidents and qualifies as an exception to the patient authorization for disclosure requirement.

The DOH is moving toward using electronic reporting more and more as a way to satisfy the data collection component of the notifiable conditions rules.

Advantages of electronic reporting:

- Streamlines the process for data collection.
- Allows for central collection of data (it will be electronically distributed to the appropriate DOH agency or county health jurisdiction).
- Allows more timely data collection.
- Allows for more accurate data collection.
- Reduces the cost for laboratories.

How will it work:

- Laboratories will be brought into this process individually (the goal of the project is to bring many of the largest laboratories on-line in the next 18-24 months)
- DOH will be working with laboratories that have the capability of creating an HL7 message and have some understanding about LOINC and SNOMED coding systems. In fact, for laboratories willing to work with DOH, we will be able to provide them with a license to use SNOMED coding.

How will laboratories be brought into the system:

- Identify key contacts at the laboratory.
- Identify the person that will be the main contact.
- Negotiate a preliminary agreement on what data is to be collected; how to ensure that the data moving across is the correct data; restrictions on the use of the data; define communication channels, etc.
- Determine the network architecture, data flow, and implementation model.
- Negotiate implementation timeline and acceptance criteria.
- Negotiate specifics of HL7 message.
- Negotiate the process for reference table updates.
- Execute implementation contract.
- Establish a production environment:
  - Review the technical specifications.
  - Send test messages.
  - Transition to production system.
  - Conduct on-going testing and data validation.
- Sign-off on electronic reporting as the sole source of reporting.

If laboratories have questions about this process, please contact Greg Smith at (206) 361-2924 or by e-mail at greg.smith@doh.wa.gov.

Educational Materials Available

The Office of Laboratory Quality Assurance has the following educational materials available on request or on-line:

- Description of the On-site Survey Process
- Medical Test Site Checklist (All Specialties)
- Pre-inspection Self-assessment Checklists (Test Specific)
  - Aerobic cultures
  - Gram stains
  - Moderate complexity testing kits
  - Microscopic examinations
  - Testing in dermatology practices
  - Moderate complexity chemistry testing
  - Moderate complexity hematology testing
- Developing a Quality Assurance Plan
- Proficiency Testing or Biannual Verification of Accuracy
- Suggestions for Biannual Verification of Accuracy
- Personnel Qualifications and Responsibilities
- Good Laboratory Practices with Waived Test Systems

The LQA website address is: http://www.doh.wa.gov/hsqa/fsl/LQA_Home.htm
Select the side-bar "Medical Test Site Surveys"
Select "Pre-Survey Information"

Medical Test Site License Fees Notice of Possible Rule Making

A pre-proposal statement of inquiry, CR-101, regarding the Medical Test Site license fees has been filed with the Office of the Code Reviser and is listed in the State Register, Issue 02-03, published on February 6, 2002. The purpose of this notice is to alert interested parties that revisions to the Medical Test Site (MTS) license fee structure (WAC 246-338-020, 246-338-990) are being considered. The proposed changes were outlined in the March 2001 issue of *Elaborations*.

Since the fee increase will be above the I-601 limits for many categories of license, a request for exemption from I-601 is included in the Department of Health's supplemental budget request, and must be approved by the 2002 legislature.

If you have any questions, please contact:
Gail Neuenschwander
Telephone: (206)361-2805
Email: gail.neuenschwander@doh.wa.gov

Waived Testing Helpful Hints

Q: Where can I find information about whether a specific test or test kit is categorized as waived, moderate, or high complexity?

A: This information can be found at the following website:

http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCLIA/search.cfm

Q: Where can I find a list of the current waived tests?

A: This information can be found at the following website:

http://www.doh.wa.gov/hsqa/fsl/LQA_Home.htm

Select the side-bar "Medical Test Site Licensing"
Select "Certificate of Waiver"

Calendar of Events

PHL Training Classes

Advanced Hematology

April 2	Shoreline
April 3	Shoreline

Urine Sediments

May 8	Shoreline
May 9	Shoreline

Point of Care Testing

June 21	Shoreline

WSSCLS/NWSSAMT Spring Meeting

April 25-27 Everett

Northwest Medical Laboratory Symposium

October 16 - 19 Portland

9th Annual Clinical Laboratory Conference

November 11 Seattle

Contact information for the events listed above can be found on page 2. The Calendar of Events is a list of upcoming conferences, deadlines, and other dates of interest to the clinical laboratory community. If you have events that you would like to have included, please mail them to ELABORATIONS at the address on page 2. Information must be received at least one month before the scheduled event. The editor reserves the right to make final decisions on inclusion.

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